REMARKS

Claims 19, 22-31, and 52-55 are pending in this application. Claim 24 has been amended herein to clarify that which the Applicant regards as the invention. Claim 24, as amended, is supported by the specification as filed at page 6, line 29. No new matter has been added. Upon entry of the amendments made herein, claims 19, 22-31, and 52-55 will be pending in the application.

THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH, SHOULD BE WITHDRAWN

Claim 24 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite in the recitation of the term "low pH." Specifically, the Examiner alleges that "[a]lthough scientifically it is understood that a low pH can be an acidic condition, it does not preclude the term from meaning a basic or alkaline pH."

Applicant has amended claim 24 to remove any reference to the term "low pH." Accordingly, Applicant respectfully requests that the rejection of claim 24 under 35 U.S.C. § 112, second paragraph, be withdrawn.

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, SHOULD BE WITHDRAWN

Claims 19, 22-31, and 52-55 stand rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which, allegedly, is not described in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention.

The Examiner brings to Applicant's attention the "Revised Interim Written Description Guidelines - Training Materials," which provides a synopsis and examples to determine whether the written description requirement of 35 U.S.C. § 112, first paragraph is satisfied. The Examiner states that the written description guidelines describe "6 distinguishing characteristics that must be provide[sic] in order to fulfill the written description of a *product*..." (italics added). Office action at 3. Such characteristics include "partial structure, physical/chemical properties, functional characteristics, and known or disclosed correlation between structure and function." *Id.* The Examiner alleges that the present invention only discloses the general structure of the hsp-peptide complex, but does not disclose or describe the characteristics listed above. The Examiner further alleges that "[t]here is a myriad of possible peptides that can be associated with the HSP-complex, of which the instant specification has not described." The Examiner concludes by stating that "[a]bsent this information, one of skill in the art cannot readily make a determination of the contents of the claimed peptide composition, the structure of the composition, or any distinguishing characteristics associated with the composition, because the peptides isolated from the HSP complex differ and are not necessarily derived from the same protein." Office action at 3-4. Applicant respectfully submits that the Examiner's written description rejection is in error.

Applicant again reminds the Examiner that claims 19, 22-31 and 52-55 are product-by process claims. By definition, product-by-process claims recite a product or composition of matter (or its elements) by the process by which it is made, rather than by its structural or chemical characteristics. *See* MPEP § 2173.05 (p) at page 2100-210 (8th ed., Rev. 1, Feb 2003). A careful review of the rejected claims (claim 19, and dependent claims 22-31 and 52-55) reveals that they are indeed product-by-process claims, *i.e.*, they define the claimed product in terms of the process by which it is made. In particular, the preamble of

claim 19 sets forth, "a composition", by the process by which it is made, "a method comprising the steps of: purifying...; releasing...and recovering...". There is a distinction in the case law between product claims and product-by-process claims. *See Fiers v. Revel*, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993), where the Federal Circuit stated that "in addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process," citing *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991). In addition, the MPEP § 2163 states that "disclosure of only a method of making the invention and the function may not be sufficient to support a product claim other than a product-by-process claim." MPEP § 2163 II (A)(3)(a)(i) at page 2100-168 (8th ed., Rev. 1, Feb 2003).

The case law teaches that the mere fact that a claim to a composition is couched in terms of the process by which said composition is made, is not enough to render the claim objectionable. The U.S. Court of Customs and Patent Appeals has stated that "it is well established that product claims may include process steps to wholly or partially define the claimed product." *In re Luck*, 476 F.2d 650, 653, 177 USPQ 523 (CCPA 1973). Further, the Patent and Trademark Office Board of Appeals has held that "[i]t is proper to describe a composition or its component in terms of its method of preparation when more direct means of description are not available." *Ex parte Pantzer and Feier*, 176 USPQ 141, 142 (Pat. & Tr. Office Bd. App. 1972). Claims directed to a product-by-process are proper. MPEP § 2173.05 defines and explicitly approves the use of a product-by-process claim format. A "product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper." MPEP § 2173.05(p) at page 2100-210 (8th ed., Rev. 1, Feb 2003).

In view of the foregoing, the outstanding rejection concerning lack of written description has been overcome. Accordingly, Applicant requests that the Examiner reconsider and withdraw the rejection of claims 19, 22-31 and 52-55.

THE REJECTION UNDER 35 U.S.C. § 102(b) SHOULD BE WITHDRAWN

Claim 19 is rejected under 35 U.S.C. § 102(b) as being anticipated by Berliner *et al.* (U.S. Pat. No. 5,210,076; "Berliner"), as evidenced by Noessner, E., *et al.*, 2002, J. Immunol. 169:5424-5432 ("Noessner"). Specifically, the Examiner alleges that Berliner discloses a "tyrosinase protein wherein the said protein is found in [a] compound comprising a pharmaceutically acceptable carrier." Office action at 4. Further, the Examiner alleges that as evidenced by Noessner, "tyrosinase is a peptide which can be associated with the HSP70 protein thereby forming a complex, and because the claims are drawn to a product by process, and because the product being produced [is] already known, the process by which the product is made does not carry any patentable weight." Office action at 5. Applicant respectfully submits that Berliner is not sufficient to render claim 19 anticipated.

The legal standard for anticipation is one of strict identity. A claim is anticipated only if each and every element set forth in the claim is found in a single prior art reference. *Verdegaal Bros. Inc. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In other words, there must be no difference between the claimed invention and the reference disclosure as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). When examining a product-by-process claim for novelty, one looks to the final product of the claimed process, disregarding the process limitations. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted); *see also* MPEP § 2113

2100-56 (8th ed., Rev. 1, Feb 2003). As discussed below, the tyrosinase enzyme discussed in Berliner cannot anticipate the product of the instant claims.

Berliner describes the use of melanin, its variants, analogs and derivatives, and other substances, including tyrosinase, to increase the concentration of melanin in the tissue of patients with certain neurodegenerative diseases which result in a loss of melanin, such as Parkinson's disease, Alzheimer's disease, retinitis pigmentosa and dementia. *See* Berliner at col. 1, lines 11-37. Tyrosinase is described as an enzyme that plays a key role in the synthesis of melanin and its derivatives. Berliner at col. 7, lines 61-62. However, Berliner does not disclose or suggest the isolation of a population of peptides noncovalently associated with a stress protein in a mammalian tumor cell.

The teaching of Noessner, a post-filing date reference, does not render Berliner anticipatory of the product claimed herein. Noessner describes the role of a tumor-derived heat shock protein (hsp70) in mediating the transfer of a tyrosinase peptide to human immature dendritic cells (DCs) by receptor-dependent uptake. Noessner reports that this hsp70-tyrosinase peptide complex mediates T cell stimulation by instructing the DCs to cross-present tumor-derived antigenic peptides of the melanocytic lineage. Thus, Noessner teaches that a tyrosinase peptide is contained within the population of peptides complexed to hsp70 in a melanoma cell line.

However, the present invention relates to a *population* of peptides that are recovered from non-covalently complexed stress proteins. Moreover, the recovered population of peptides encompassed by the claims comprises a complex and heterogeneous mixture of peptides, *i.e.*, a plurality of different peptides. *See* Liu, C. *et al.*, "*De novo* identification of the ever-elusive gp96-associated peptides," Int'l Conf. on Heat Shock

Proteins in Immune Response, Farmington, CT, October 6-9, 2002, Abstract, p. 31 (Reference GE in the revised Form PTO-1449 submitted herewith).

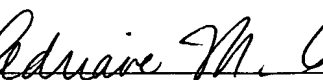
Berliner does not teach a population of peptides as set forth in the instant claims. Berliner teaches one protein, *i.e.*, tyrosinase. Such a protein is not the same as a population of peptides recovered from stress proteins. Accordingly, Applicant submits that Berliner alone or evidenced by Noessner, fails to teach each and every element of the claimed invention. Thus, Berliner cannot anticipate the invention claimed herein. Applicant respectfully requests that the rejection based on Berliner be reconsidered and withdrawn.

CONCLUSION

Applicant respectfully requests that the remarks of the present response be entered and made of record in the instant application. Claims 19, 22-31 and 52-55 fully meet all the statutory requirements for patentability. Withdrawal of the Examiner's rejections and early allowance and action for issuance are respectfully requested.

Respectfully submitted,

Date November 20, 2003



32,605

Adriane M. Antler (Reg. No.)

PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, New York 10036-2711
(212) 790-9090

Enclosures